b.) Remarks

Claims 42, 44, 63, 64 and 81 are amended to correct typographical errors only. Accordingly, no new matter has been added.

The sole remaining issue is the rejection of claims 42-53, 63-70 and 72-102 under 35 U.S.C. §103(a) being obvious over Tsushima US 6,036,974 and Roche US 5,075,114, optionally in view of Morimoto EP 0 650 826.

In support of the rejection, the Examiner argues that:

> (i) a tablet compressing method using tabletting machine with lubricant spraying mean,
>
> (ii) a method for preparation of tablet comprises preparing tabletting material containing medicines and excipients, coating on the surface of the tabletting material a lubricant such as stearic acid and stearic acid metal salt, coating the surface of the punches with lubricant,
>
> (iii) a medicament tablet comprising granules coated with polymers blend,
>
> (iv) a method for preparation of tablet comprises preparing tabletting material containing medicines and excipients, coating on the surface of the tabletting material a lubricant such as stearic acid and stearic acid metal salt, coating the surface of the punches with lubricant, filling the die with the coated tabletting material and compressing to obtain tablet, and
>
> (v) a medicament tablet comprising granules coated with polymers blend and the resulting coated granule were then compressed into tablet from using tabletting machine having die wall and punches

are all variously taught by the prior art.

Further, the Examiner argues that the percent amount of lubricant being coated onto the surface of the die and punches will not support patentability without evidence indicating such concentration is critical, because the discovering of the optimum or workable ranges is routine.

This rejection is respectfully traversed. Prior to setting forth their bases for traversal, however, Applicants would briefly like to discuss the salient features of the present invention and *inter alia* its patentable nature over the prior art.

As the Examiner is well-aware, the present invention is characterized by following points (technical features):

1. The molding material (the material comprising the tablet) does not include a lubricant (such as stearic acid metal salt or stearic acid) therein.

2. A minute amount of lubricant is provided on only the surface of the compressed tablet.

3. A lubricant is applied only to a die and a pair of punches for tabletting.

4. The molding material is manufactured at low tableting pressure of 0.7 to 1.3 ton/cm^2.

According to the above-mentioned features 2 and 3, the following special effects can be achieved when compared with the tablet disclosed by Roche which includes a lubricant in the molding material,

- The tablet of the present invention has a sufficient (practical) hardness even when the tablet is compressed at low tableting pressure (point 4).
- The disintegration time among tablets is consistent because the effect by the water repellency of the lubricant is reduced.
- Moreover, the present invention produces a functioning tablet from granules containing an active substance, which granules bear a coating film that is destroyed when compressed at tableting pressure greater than 1.3 ton/cm^2

The cited prior art does not achieve these features, even when taken collectively.

Tsushima relates to a producing an aqueous molding tablet by removing a wet tablet from the mold after compression, and drying the tablet taken out from the mold (column 1, line 36 to column 3, line 9). On the other hand, the present invention does not require such a drying process and the tablet of the present invention is produced only by compression. In contrast, in the present invention, tablet hardness is essentially affected by the tableting pressure of the tableting machine. In contrast, hardness of Tsushima's aqueous molding tablet is unaffected by the tableting pressure and the tablet can be compressed at vastly smaller tableting pressure.

As to the technical feature 4, Tsushima proposes a method of producing an aqueous molded tablet in which a wet paste is filled in mold 42 (at process A) and then a lubricant is coated thereon (at process B). In Tsushima's method, no lubricant is provided in the inner circumferential wall of mold 42. That is, Tsushima applies lubricant only after

a wetted paste is filled in the mold 42 (column 5 lines 11 to 22, column 5, lines 27 to 35). Moreover, Tsushima applies lubricants directly on the upper and lower paste surfaces. However, in the present invention, a lubricant is directly applied to the punches and dies in order to prevent the lubricant from being attached on the tablet as far as possible.

Moreover, Roche cannot be combined with Tsushima. Roche coated granule releases medicament in the GI tract (column 5, lines 24-27). The coating film is necessarily damaged due to Tsushima's 10% by weight ethanol or water. Therefore, if Roche is incorporated into the method of Tsushima, the function of granule is damaged in the produced tablet, in direct contrast to the present invention.

Since none of the cited art teaches granules with fragile coatings, Applicants respectfully submit for at least that reason there is no *prima facie* obviousness in the prior art to achieve their tableting method.

Moreover, Applicants' lower limit (0.7 ton/cm^3) of tableting pressure in the technical feature 4 is *per se* critical since Applicants have determined tablets produced at less than that pressure do not have sufficient hardness. (In Tsushima, a tablet can be compressed less than the lowest limit, however, because the molding material is aqueous.) Further, Tsushima describes a tableting pressure of 5 to l00Kg per tablet (column 2, lines 9 to 13) which is a full order of magnitude lower than the tabletting pressure of the present invention.

Further, in any event, Applicants' dependent claims recite patentable and unobvious subject matter in their own right. For instance, Tsushima is critical to the

Examiner's analyses but Tsushima requires an aqueous tabletting solution. In contract, claims 101 and 102 require that the molding material be dry.

Moreover, even if there is, *arguendo* some *prima facie* obviousness, such is necessarily rebutted by the evidence already of record which shows that the present invention provides tablets without damaging the function of its constituent granules. This advantage is of clear benefit to those of ordinary skill in the art and is not taught or suggested by any of the prior art, whether taken singly or collectively.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 42-53, 63-70 and 72-102 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Lawrence S. Perry/
Lawrence S. Perry
Attorney for Applicants
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

LSP\ac

FCHS_WS 2074491_1.DOC